

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ARTHUR C. COFFEY

Appeal 2009-012595
Application 10/276,778
Technology Center 3700

Decided: March 8, 2010

Before ERIC GRIMES, RICHARD M. LEBOVITZ, and STEPHEN
WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to wound care bandages and methods of promoting wound healing. The Patent Examiner rejected the claims as failing to comply with the written description requirement and as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

STATEMENT OF THE CASE

The invention concerns wound care bandages comprising a small intestine submucosa (SIS) layer and methods for using the bandage, along with a vacuum source, to promote wound healing. According to the Specification, "SIS has been described as a natural acellular biomaterial used to repair, support, and stabilize a wide variety of anatomical defects and traumatic injuries." (Spec. 1:15-16). The Specification also states that the method of the invention "controllably draw[s] fluid from the surrounding tissue and into an SIS layer placed on the wound, thereby enhancing the healing and restructuring properties of the SIS." (*Id.* at 4:9-11).

Claims 3-5, 10-13, 19-26, and 29-35, which are all the pending claims, are on appeal. Claims 3, 32, and 35 are representative and read as follows:

3. A wound care bandage comprising:
a small intestine submucosa (SIS) layer for placement on a wound,
a cover for placement over the wound to provide a sealed environment with which a vacuum source communicates, and
a structure for placement between the SIS layer and the cover and configured to provide a vacuum space, wherein no sutures and no staples are present in the resulting wound care bandage to hold the SIS layer in place during communication of negative pressure to the vacuum space by the vacuum source.

32. The method of claim 30, wherein the structure comprises a ring having an aperture defined by an inner wall of the ring and wherein the vacuum space is defined by the first SIS layer, the cover, and the inner wall of the ring.

35. The method of claim 29, wherein the vacuum is generated for a sufficient period of time to begin integration of the first SIS layer into the wound surface, and further comprising the step of placing a second SIS layer over the first SIS layer.

The Examiner rejected the claims as follows:

- claims 3, 19, 21, 26,¹ and 29 under 112, first paragraph, as failing to comply with the written description requirement, and
- claims 3-5, 10-13, 19-26, and 29-35 under 35 U.S.C. § 103(a) as obvious over the combination of Argenta² and Whitson³.

WRITTEN DESCRIPTION

The Issue

The Examiner's position is that claims 3, 19, 21, 26 and 29 (*see* fn. 1) contain subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed. (Ans. 3). Specifically, the Examiner found that the claim limitation "no sutures and no staples" is new matter because "Applicant's original disclosure does not disclose not using sutures or staples." (*Id.* at 4). According to the Examiner, "[f]igures, not showing the features, are not sufficient support of the negative limitations." (*Id.*).

Appellant contends that "[t]he drawings of the present application clearly demonstrate that Appellant is in possession [of the disputed claim

¹ Claim 26 contains the same claim language that the Examiner found to be new matter in claims 3, 19, 21 and 29. Appellant notes that the Examiner "appears to have overlooked listing independent claim 26" in the rejection and therefore "assumes that this rejection was intended to be made against claims 3, 19, 21, 26 and 29." (App. Br. 27; Reply 26-27).

² US Patent No. 5,636,643 issued to Argenta et al., Jun. 10, 1997.

³ US Patent No. 5,755,791 issued to Whitson et al., May 26, 1998.

phrase],” i.e., wound care bandages/methods wherein no sutures or staples are present/used. (App. Br. 29).

The issue with respect to this rejection is whether Appellant has established that the claim phrase “no sutures and no staples” is supported by the instant disclosure and is not new matter.

Findings of Fact Related to the Written Description Issue

1. The Specification as originally filed does not state or explain that no sutures and no staples are present in the wound care bandage to hold the SIS layer in place .
2. The Specification as originally filed does not state or explain that no sutures and no staples are used to hold the SIS layer in place.
3. Specification Figures 1 and 3-5 illustrating the wound care bandage of the invention do not depict the use of any sutures or staples. (Spec. Figs. 1 and 3-5).

Principles of Law

“The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at [the] time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language.” *In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983)(citations omitted). “The content of the drawings may also be considered in determining compliance with the written description requirement.” (*Id.*).

Analysis

We agree with Appellant that the Examiner has not provided sufficient factual basis to support finding that the negative limitation in question introduces new matter into the application disclosure. Rather, the Examiner has merely relied upon the fact that the Specification does not expressly describe not using sutures or staples. As Appellant has correctly asserted (App. Br. 26-29) the Specification as a whole, including the Figures 1 and 3-5 which do not depict the use of sutures or staples, reasonably conveys to a person having ordinary skill in the art that the inventors had possession of the subject matter in question at the time the present application was filed. *See Kaslow*, 707 F.2d at 1375.

Accordingly, we reverse the Examiner's rejection of claims 3, 19, 21, 26 and 29 under § 112, ¶ 1.

OBVIOUSNESS

The Issue

The Examiner's position is that "Argenta disclosed a wound care bandage comprising a cover ... configured for placement over the wound to provide a sealed environment, and a structure ... for placement between a skin graft or SIS layer and the cover to provide a vacuum space." (Ans. 4). The Examiner found that Argenta disclosed using the bandage with skin grafts. The Examiner also found that Argenta taught that applying a "negative pressure improves blood flow to the wound and improves attachment of the grafted tissue." (*Id.*)(citing Argenta, 14:5-15). Additionally, the Examiner found that Argenta disclosed using "alternative wound closure methods other than suturing or stapling...." (Ans. 4)(citing

Argenta, 1:49-55). However, the Examiner found that Argenta did not disclose that the skin graft is one or more SIS layers. (Ans. 4).

Next, the Examiner found that Whitson disclosed a perforated submucosal tissue graft construct, e.g., from the small intestine (i.e. SIS), comprising strips of submucosa tissue that “are useful in promoting regrowth and healing of damaged or diseased tissue structures. (Ans. 4)(citing Whitson, 3:25-30). The Examiner also found that one or more SIS layers can be placed on a first SIS layer. (*Id.* at 5).

According to the Examiner, it would have been obvious for a person of ordinary skill in the art at the time the invention was made to have employed Whitson’s SIS layer as the skin graft in Argenta’s wound treatment to promote regrowth and healing of damaged or diseased tissue structures. (*Id.*).

Regarding claim 32, the Examiner further found that Argenta did not disclose a vacuum space defined by the inner wall of a ring. (Ans. 6). However, the Examiner also found that Appellant’s Specification did not provide any “criticality to the structure providing space between the SIS layer and the cover layer.” (*Id.*). Additionally, the Examiner found that the Specification did not disclose “that a specific structure provides an advantage, is used for a particular purpose, or solves a stated problem.” (*Id.*). Therefore, the Examiner determined that at the time of the invention, it would have been an obvious matter of design choice to have made the structure out of a ring. (*Id.*). Further, the Examiner found that a skilled artisan would have expected Argenta’s bandage and Appellant’s invention “to perform equally well with either the foam pad structure used by Argenta,

or the claimed ring structure because both materials would perform the same function of providing a vacuum space.” (*Id.* at 7).

Regarding claim 35, the Examiner determined that the method of the claim would have been obvious to a skilled artisan at the time of the invention because Argenta disclosed generating the vacuum to begin integration of the graft into the wound, and Whitson taught the use of multiple SIS layers. (*Id.*).

Appellant contends that a skilled artisan would not combine the teachings of Argenta and Whitson. (App. Br. 12). According to Appellant, “[i]t is known that collagen matrix materials, like SIS, need to be kept moist when in use on wounds.” (*Id.* at 13). Therefore, Appellant asserts that a skilled artisan at the time of the invention would be led away from combining Argenta’s device that removes fluid from the wound site with Whitson’s SIS layer that needs to be kept moist. (*Id.* at 12-19).

Appellant also contends that even if one skilled in the art combined the teachings of Argenta and Whitson, the combination would not read on the instant invention because the references do not teach or suggest the recited (a) structure of independent claims 3, 19, 21, 26, and 29, (b) ring element of claim 32, and (c) second SIS layer of claim 35. (*Id.* at 19-26).

The issue with respect to this rejection is whether the evidence supports the Examiner’s findings and conclusion that the claimed wound healing bandages and methods would have been obvious over the combined prior art to a person of ordinary skill in the art at the time the invention was made.

Findings of Fact Related to the Obviousness Issue

4. Argenta teaches a method of treating tissue damage in burns and in wounds which “comprises applying a negative pressure to a wound sufficient in time and magnitude to promote tissue migration and thus [to] facilitate closure of the wound.” (Argenta, Abstract).
5. Argenta describes an apparatus “in which a fluid impermeable wound cover is sealed over a wound site.” (*Id.*).
6. Argenta disclosed placing a screen, in the form of an open-cell foam screen or rigid porous screen, beneath the wound cover over the wound to prevent overgrowth of tissue in the wound area. (*Id.* at 3:23-27).
7. Argenta disclosed that a vacuum source supplies suction within the wound cover over the treatment site. (*Id.* at Abstract; 3:17-20).
8. Argenta disclosed that the screen means connected to the vacuum source by a flexible hose. (*Id.* at 5:17-20).
9. Argenta disclosed that applying negative pressure to a wound provides benefits such as faster healing, increased formulation of granulation tissue, closure of chronic open wounds, reduction of bacterial density within wounds, and enhancement of flap and graft attachment. (*Id.* at 2:53-58).
10. Argenta disclosed a vacuum apparatus that includes a control device for halting suction at the wound site in the event that an excessive quantity of exudate has been collected. (*Id.* at 3:45-48).
11. Argenta also disclosed a control device for controlling the frequency and length of time that negative pressure is applied to the wound. (*Id.* at 3:48-51).

12. Argenta disclosed applying negative pressure to a wound to promote and enhance wound healing by preferably “using a negative or reduced pressure ranging from 0.01 to 0.99 atmospheres....” (*Id.* at 12:57-59).
13. Argenta does not disclose using a SIS layer for placement on a wound.
14. Whitson disclosed a perforated submucosal tissue graft construct comprising strips of submucosa tissue for enhanced mechanical and tissue remodeling properties. (Whitson, Abstract).
15. Whitson disclosed that “[s]mall intestinal tissue is a preferred source of submucosal tissue....” (*Id.* at 3:28-30).
16. Whitson disclosed preparing a large submucosa tissue graft from small or multiple pieces, the individual pieces of which are directionally specific, governed by the collagen orientation of the tissue and thus contributing to its physical properties. (*Id.* at 1:30-43).
17. Whitson disclosed that perforations allow extracellular fluids to pass through the tissue graft material, decreasing fluid retention within the graft and enhancing the remodeling properties of the tissue grafts. (*Id.* at 2:53-63).

Principles of Law

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). There must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *In re Kahn*, 441 F.3d 977, 988

(Fed. Cir. 2006). It is well settled that “claims in an application are to be given their broadest reasonable interpretation consistent with the specification and that claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art.” *In re Sneed*, 710 F.2d 1544, 1548 (Fed. Cir. 1983).

Analysis

Claims 3-5, 10-13, 19-26, 29-31 and 33-34

We are not persuaded that the Examiner erred in combining the teachings of Argenta and Whitson. Appellant contends that a skilled artisan at the time of the invention would have understood that collagen matrix materials, like Whitson’s SIS layer, need to be kept moist. (App. Br. 13). Appellant asserts that a skilled artisan would not have combined Whitson’s SIS layer with Argenta’s device because it uses a vacuum source to draw fluids away from the wound. (*Id.* at 15). However, we find that this argument does not properly consider the ordinary skill in the art. As the Examiner explained, a skilled artisan would understand that “the use of a vacuum to remove excess wound exudate would not [be used to] remove all of the fluid from the graft area.” (Ans. 9). Rather, the skilled artisan, e.g., a physician, would set a proper suction power to meet the needs of the patient, which would not involve removing “all the fluid from the wound because the fluid surfacing through the wound carr[ies] nutrients that aid in the healing process.” (*Id.*). In other words, a skilled artisan would have the understanding and skill to use the vacuum source to remove excess fluids from the wound site while sufficiently maintaining a moist environment. The Examiner’s reasoning is consistent with the teachings of the prior art.

Specifically, Whitson described a tissue graft that comprises a plurality of perforations to “allow extracellular fluids to pass through the tissue graft material, *decreasing fluid retention* within the graft and enhancing the remodeling properties of the tissue grafts.” (FF16)(Emphasis added). Argenta disclosed a vacuum apparatus that includes a control device for halting suction at the wound site in the event that an excessive quantity of exudate has been collected (FF10) and a device for controlling the frequency and length of time that negative pressure is applied to the wound (FF11). Additionally, Argenta disclosed applying negative pressure to a wound to promote and enhance wound healing by preferably “using a negative or reduced pressure ranging from 0.01 to 0.99 atmospheres....” (FF12). We note that this is the same range of pressure disclosed in the instant Specification. (Spec. 10:23-24). Thus, Argenta provided a controllable vacuum apparatus to decrease fluid retention, as taught by Whitson, and disclosed a range of negative pressure sufficiently broad as to allow an artisan to skillfully select a pressure and time period of use that beneficially bolsters wound healing while maintaining adequate moisture at the wound site. Therefore, we conclude that the Examiner’s rejection is properly based upon a “combination of familiar elements according to known methods ... [that] does no more than yield predictable results.” *KSR.*, 550 U.S. at 416.

Appellant also contends that “[e]ven if one skilled in the art were to combine the teachings of Argenta and Whitson, none of the independent claims 3, 19, 21, 26, and 29 would read on the resulting structure....” (App. Br. 19). Specifically, Appellant asserts that the claim phrase “wherein no sutures and no staples” are either present in the wound care bandage or used to hold the SIS layer in place distinguishes the claims over the structure and

method of the combined prior art. (*Id.*). In particular, Appellant relies on Argenta's example in which negative pressure was applied after "flaps were raised and then **sutured back in place with single, interrupted sutures of 3-0 nylon.**" (*Id.* at 20)(quoting Argenta, 17:65-67). According to Appellant, "one skilled in the art, reading Argenta in its entirety, would conclude that sutures are needed with flaps or grafts, or Whitson's structure if substituted for the flaps or grafts mentioned in Argenta." (*Id.* at 20).

We disagree. While Argenta provided an example in which sutures are used to hold a flap in place, the reference does not teach or suggest that using sutures is either required or necessary where a flap is employed. Additionally, Argenta does not provide any examples using sutures or staples with a graft. Rather, Argenta's disclosure related to grafts is essentially limited to the fact that "[w]ounds that have exhibited positive response to treatment by the application of negative pressure include ... various lesions to which flaps or grafts have been attached." (Argenta, 2:58-62). Argenta does not disclose that such attachment must be accomplished by the use of sutures or staples, or even any mechanical means. Moreover, as the Examiner explained, Argenta specifically described problems that are often encountered in wound treatments involving the use of sutures. (Ans. 10)(citing Argenta, 1:49-55). Similarly, while Whitson disclosed tissue graft constructs that "can be further manipulated (i.e. cut, folded, sutured, etc.)" (Whitson, 6:56-59) Whitson also cannot be said to teach or suggest that sutures are required to hold its grafts in place. Consequently, we do not find that the combined references teach away from the disputed claim phrase when employing Whitson's graft in Argenta's method.

Claim 32

Claim 32 recites “The method of claim 30, wherein the structure comprises a ring having an aperture defined by an inner wall of the ring and wherein the vacuum space is defined by the first SIS layer, the cover, and the inner wall of the ring.”

Claim 30 recites, “The method of claim 29, wherein creating the vacuum space includes positioning a structure between the first SIS layer and the cover to provide the vacuum space.”

Independent claim 29 recites “applying a first small intestine submucosa (SIS) layer to a wound surface....”

Appellant asserts that claim 32 should be allowable for the same reasons asserted regarding the group of claims including independent claim 29. (App. Br. 23). We do not agree that this group of claims was nonobvious, for the reasons just explained.

Appellant also contends that Argenta and Whitson do not teach or suggest the ring element recited in claim 32. (*Id.*). Additionally, Appellant asserts that the ring element is not merely a design choice, but has a mechanical function.

We agree that the Examiner has not established that the prior art teaches or suggests the limitation of claim 32. In the Answer, the Examiner stated that “Argenta does disclose a ring (59, 89, 109, or 622) on the inner wall of the vacuum space (figs. 10-11) that is defined by the cover (612) and the graft layer.” (Ans. 10). However, we do not find that the Examiner has established that Argenta elements 59, 89, 109, or 622 meet the claimed structure. As Appellant asserted in the Reply Brief, claim 32 depends from claims 29 and 30, which together require the first SIS layer to be situated

between the structure comprising a ring, and the wound. (Reply Br. 40). The Examiner has not established that Argenta's elements satisfy such an arrangement. *See Kahn*, 441 F.3d at 988. Further, we agree with Appellant (Reply Br. 40) that the ring element in claim 32 is not simply a design choice, but has a mechanical function that is defined by the claim, i.e., providing an inner wall defining part of the vacuum space.

Claim 35

Appellant asserts that claim 35 should be allowable for the same reasons asserted regarding the group of claims including independent claim 29. (App. Br. 26). We do not agree that this group of claims was nonobvious, for the reasons previously explained.

Appellant also contends that the Examiner erred in rejecting claim 35 because "neither Argenta nor Whitson ... teach or suggest placing a second SIS layer over a first SIS layer that has begun to integrate into a wound surface." (*Id.*). According to Appellant, Argenta does not teach a SIS layer and further does not teach or suggest that "a second flap or graft is placed over the first one after the first one begins to integrate into the wound surface." (*Id.*). Appellant also asserts that Whitson teaches graft constructs that have multiple submucosa layers "attached together at the time of manufacture for later use as a single unitary piece," and does not contemplate applying a second SIS layer to a wound after a first one begins to integrate. (*Id.*).

This argument is not persuasive. Claim 35 recites, "The method of claim 29, wherein the vacuum is generated for a sufficient period of time to begin integration of the first SIS layer into the wound surface, and further comprising the step of placing a second SIS layer over the first SIS layer."

The Examiner reasoned that “claim 35 does not require that the second SIS layer be placed over the first SIS layer *after* the first one begins to integrate into the wound surface.” (Ans. 11, emphasis added). In the Reply, Appellant acknowledges that the Examiner’s interpretation of claim 35 “is not entirely unreasonable.” (Reply Br. 40). Appellant additionally asserts that the claim “could possibly stand to be amended to clarify” the “intended meaning” of the claim, i.e., “that the second SIS layer is placed over the first SIS layer after the first SIS has begun to integrate into the wound surface.” (*Id.* at 41).

“[C]laims in an application are to be given their broadest reasonable interpretation consistent with the specification and [the] claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art.” *Sneed*, 710 F.2d at 1548. Appellant has not identified any portion of the Specification that provides insight regarding the disputed claim language. Nor has the Appellant directed us to any persuasive evidence that a more narrow interpretation of claim 35 applies, i.e., that the second SIS layer is placed over the first SIS layer *after* the first one begins to integrate into the wound surface. (*See* Reply. Br. 40-41). Therefore, we construe the phrase “wherein the vacuum is generated for a sufficient period of time to begin integration of the first SIS layer into the wound surface, and further comprising the step of placing a second SIS layer over the first SIS layer” broadly to include the step of placing a SIS layer over a first SIS layer at a time irrespective to the integration of the first SIS layer onto the wound. It is the applicants’ burden to precisely define the invention. *In re Morris*, 127 F.3d 1048, 1056 (Fed. Cir. 1997).

Therefore, giving claim 35 its broadest reasonable interpretation, we find that the Examiner reasonably determined that the claimed invention would have been obvious to a person of ordinary skill in the art at the time of the invention who reviewed Argenta and Whitson. In particular, the Examiner found that Argenta disclosed using a vacuum source to improve the integration of a skin graft into a wound. (Ans. 7)(citing Argenta, 12:51-52). Whitson described preparing graft constructs by placing strips of submucosal tissue one on top of the other to provide enhanced mechanical strength and a greater surface area than any one individual strip. (Whitson Abstract; 5:20-23; Figs. 1a-1c). Thus, we find that a skilled artisan who reviewed the references would understand that layering a second SIS layer onto a first layer would beneficially provide enhanced mechanical strength and a greater surface area than the first layer by itself. We do not find that Appellant has established otherwise with persuasive evidence.

CONCLUSIONS OF LAW

Appellant has established that the claim phrase “no sutures and no staples” is supported by the instant disclosure and is not new matter.

Appellant has also established that the claimed wound healing method of claim 32 would not have been obvious over the combined prior art to a person of ordinary skill in the art at the time the invention was made.

However, Appellant has not established that the claimed wound healing bandages and methods of claims 3-5, 10-13, 19-26, 29-31 and 33-35 would not have been obvious over the combined prior art to a person of ordinary skill in the art at the time the invention was made.

SUMMARY

We reverse the rejection of claims 3, 19, 21, 26 and 29 under 112, first paragraph, as failing to comply with the written description requirement, and

we affirm the rejection of claims 3-5, 10-13, 19-26, 29-31 and 33-35 under 35 U.S.C. § 103(a) as obvious over the combination of Argenta and Whitson, and

we reverse the rejection of claim 32 under 35 U.S.C. § 103(a) as obvious over the combination of Argenta and Whitson.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

lp

FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVENUE
SUITE 2400
AUSTIN TX 78701